IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:

Tammy Pizzitola v. C. R. Bard, Inc., et al. **Case No. 2:13-cv-00249**

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE OR LIMIT CERTAIN OPINIONS AND TESTIMONY OF KEITH REEVES, M.D.

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Pursuant to Federal Rules of Evidence 702, 703, 403, and 104, Defendant C. R. Bard, Inc. ("Bard") hereby submits this Memorandum of Law in Support of Motion to Exclude or Limit Certain Opinions and Testimony of Keith Reeves, M.D. (the "Motion"). In support of its Motion, Bard respectfully shows the Court as follows:

INTRODUCTION

The plaintiff in *Pizzitola v. C. R. Bard, Inc., et al.*, Case No. 2:13-cv-00249 ("Plaintiff"), a Wave 13 Case, designated Dr. Keith Reeves as a general expert[1] based on his Rule 26 General Liability and Causation Report on the C. R. Bard Alyte Product ("Report"), which was served by the Plaintiffs' Steering Committee in MDL 2187.[2] Dr. Reeves is a former gynecologist who practiced restorative pelvic medicine. *See* Jan. 16, 2020 Deposition of Dr. Keith Reeves ("Deposition" or "Dep.") at 27:6-20.[3] Dr. Reeves retired from the practice of medicine in 2013. *See id.* Since then, Dr. Reeves' employment has consisted of providing expert testimony exclusively on behalf of plaintiffs, the majority of which are plaintiffs in transvaginal mesh MDL litigation. *See id.* at 21:15-22:4, 27:16-20.

Dr. Reeves purports to offer expert general opinions regarding Bard's Alyte Y-Mesh Graft device ("Alyte"), but has never implanted an Alyte in his career. *See* Dep. at 33:7-9. In fact, Dr. Reeves has never implanted any polypropylene product in a pelvic procedure in his career. *See id.* at 139:12-18. Despite having no experience with the Alyte or any comparable polypropylene product, Dr. Reeves intends to offer numerous opinions critical of the Alyte, including that it is

[1] A true and correct copy of Plaintiff's First Amended Designation and Disclosure of Expert Witnesses ("Plaintiff's Disclosures") is attached to the accompanying Motion as Exhibit A. True and correct copies of all other exhibits referenced in this memorandum are also attached to Bard's Motion.
[2] A true and correct copy of the Report is attached to the Motion as Exhibit B.
[3] A true and correct copy of the Deposition transcript is attached to the Motion as Exhibit C.

unreasonably dangerous and defective and not safe for implant in the human body. These opinions, however, go beyond his expertise and lack a valid basis in many instances, such that they should be excluded from trial.

SPECIFIC OPINIONS TO BE EXCLUDED[4]

Bard moves to exclude Dr. Reeves' opinions and testimony concerning:

1. Any products other than the Alyte as he has been disclosed as a generic expert only with respect to the Alyte and he disclaimed in his deposition that he is offering any generic opinions on any Bard products other than the Alyte;

2. Cancer or the risk of cancer as he has admitted that there is no causal connection between polypropylene and cancer and has said that he is not postulating any cause-and-effect relationship;

3. Bard's state of mind and/or corporate conduct;

4. Bard's warnings regarding the Alyte as he has never implanted an Alyte device, has never prepared instructions for use or warnings for a medical device, does not know the process for preparing medical device warnings, and does not know the regulations governing medical device warnings;

5. Engineering aspects of the Alyte, including its properties or performances and whether it is prone to curling, cording, roping, and fraying;

6. Safer alternative designs to the Alyte;

7. Bard's product testing and clinical trials for the Alyte; and

8. Legal standards or legal conclusions, including whether Bard acted "as a reasonable and prudent medical device manufacturer" or whether the Alyte was "defective."

Any opinions related to these subjects should be excluded in their entirety for the reasons set forth herein.

[4] Bard reserves the right to move to exclude or limit Dr. Reeves' opinions on grounds other than those set forth herein if those grounds become available subsequent to the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in this case, or supplementation of this expert witness's disclosure or Report.

LEGAL STANDARD

The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). In accordance with those rules, trial judges must serve as gatekeepers to the admission of scientific testimony.[5] *See id.* at 589. This gatekeeping function applies not only to "scientific" testimony, but also to testimony based on "technical" and "other specialized" knowledge. *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 138? (1999).

Purported "expert" opinion evidence must satisfy three prerequisites before it can be admitted. *See Daubert*, 509 U.S. at 589–90; *see also United States v. Powers*, 59 F.3d 1460, 1470–71 (4th Cir. 1995) (describing Fourth Circuit's application of *Daubert* inquiry). First, the expert witness must be adequately qualified by virtue of his or her specialized "knowledge, skill, experience, training, or education. . . ." Fed. R. Evid. 702. Additionally, the expert's qualifications must be sufficiently related to the particular subjects at issue in the case. *See, e.g.*, *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170, 172 (4th Cir. 2002) (affirming the exclusion of testimony of highly credentialed expert that nevertheless lacked knowledge of specific matters essential to subject of his opinion); *Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998).

[5] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law. *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (quoting *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W. Va. 1999). In multidistrict litigation, the law of the transferee circuit governs questions of federal law. *See, e.g.*, *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (citation omitted), *aff'd*; *Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("In the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law.").

Second, the expert's opinion must be relevant such that it assists "the trier of fact to understand the evidence or to determine a fact in issue." *See* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. Mere relatedness does not necessarily establish relevancy; thus, the relevancy inquiry asks:

> [w]hether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.

Id. (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985) (internal citation omitted)). Subjects that are within the understanding of an average juror will not assist the trier of fact and must be excluded. *See, e.g.*, *United States v. Fitzgerald*, 80 F. App'x 857, 862 (4th Cir. 2003) (affirming exclusion of unhelpful expert testimony because "the basic question in this case is whether the defendant's comments and conduct amount to abusive sexual contact with minors. This appears to be a question that an average juror can decide without the assistance of expert testimony . . ."). Even if expert opinion testimony is logically relevant, it remains subject to the legal relevancy requirements of Rule 403. *See, e.g.*, *Dixon v. CSX Transp., Inc.*, 990 F.2d 1440, 1452-53 (4th Cir. 1993). Expert testimony must therefore be excluded where its probative value is substantially outweighed by the danger of unfair prejudice.

Third, the scientific or technical opinion must be reliable. *See Daubert*, 509 U.S. at 590-92. Expert witnesses must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire,* 526 U.S. at 152. To be reliable, an expert opinion must be based on scientific, technical, or other specialized knowledge

and not on belief or speculation; inferences must be derived using scientific or other valid methods. *Oglesby v. Gen. Motors Corp*., 190 F.3d 244, 250 (4th Cir. 1999).

The proponent of opinion testimony bears the burden of establishing its admissibility. *See, e.g.*, *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Where the proponent fails to establish all three prerequisites, the exclusion of expert testimony is within the trial court's sound discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997); *see also Cooper*, 259 F.3d at 200. Nevertheless, the court "may not abdicate its responsibility to ensure that only properly admitted evidence is considered by the jury. Expert opinion evidence based on assumptions not supported by the record should be excluded." *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 144 (4th Cir. 1994) (district court abused its discretion by admitting expert testimony due to the absence of factual support and the speculative nature of the underlying calculations).

The Court's scrutiny results in the exclusion of experts who: (i) go beyond the conclusions of the studies they rely upon (*see Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010)); (ii) rely on cherry-picked data (*see, e.g.*, *In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 460-61 (E.D. Pa. 2014); *In re: Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005)); (iii) assert opinions based on no evidence at all (see, e.g., Fed. R. Evid. 702(b) (requiring an expert's testimony be "based on sufficient facts or data")); and (iv) assert opinions based on evidence irrelevant to the issue under consideration without providing reasoning to support extrapolation from that evidence (*see, e.g.*, *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1314, 1320-22 (9th Cir. 1995)).

ARGUMENT

I. THE COURT SHOULD NOT ALLOW DR. REEVES TO OFFER OPINIONS ON PRODUCTS OTHER THAN THE ALYTE.

Plaintiff designated Dr. Reeves to offer general opinions regarding a single Bard product – the Alyte device. *See* Plaintiff's Disclosures at 4. Dr. Reeves disclaimed in his Deposition that he is offering opinions regarding any other Bard device other than the Alyte. *See* Dep. at 8:21-9:3. As this Court previously has ruled, Dr. Reeves therefore should not be allowed to offer opinions on products other than the Alyte, or any other undisclosed opinion.[6] *In re C. R. Bard, Inc., Pelvic Repair Sys. Products Liab. Litig.*, MDL 2187, 2018 WL 4215639, at *4 (S.D.W. Va. Sept. 4, 2018) (granting portion of Bard's motion to exclude Dr. Moore's "expected criticism regarding the poor size of the Align TO under Rule 26 on the basis that it was not included in his expert report"); *In re Boston Sci. Corp. Pelvic Repair Sys. Products Liab. Litig.*, MDL 2326, 2018 WL 8054292, at *2-3 (S.D.W. Va. May 30, 2018) (excluding opinion of Dr. Rosenzweig linking polypropylene mesh to cancer because it was not disclosed in his report); *In re Boston Sci. Corp. Pelvic Repair Sys. Products Liab. Litig.*, MDL 2326, 2018 WL 8053860, at *3 (S.D.W. Va. May 29, 2018) (excluding opinion of Dr. Margolis on grounds that his opinions were not disclosed in his expert reports).

II. THE COURT SHOULD PRECLUDE DR. REEVES FROM OFFERING OPINIONS THAT POLYPROPYLENE MESH IS ASSOCIATED WITH CANCER.

Dr. Reeves also is critical of Bard's conduct and products in light of "literature showing reports of cancer associated with polypropylene." Report at 4. This Court has previously excluded

[6] Dr. Reeves' Report appears to be littered with opinions regarding other Bard products, including the Align sling. The Alyte is a transabdominal mesh used to repair pelvic organ prolapse. The Align is a fundamentally different product as it is a mesh-based sling used to treat stress urinary incontinence. Dr. Reeves should be precluded from offering opinions regarding the Align or any other Bard product in this case.

expert testimony on cancer, stating, "[t]here will be no mention of the cancer opinion at trial," *Jones v. C.R. Bard, Inc*., No. 2:11-cv-00114, slip op. at 8 n.4 (S.D. W. Va. Jan. 6, 2014), and the Court should similarly preclude Dr. Reeves from testifying in any way about cancer for three reasons:

***First*, Dr. Reeves admitted that polypropylene does not cause cancer**. Dr. Reeves' own admissions demonstrate conclusively that there is no valid cancer risk in connection with polypropylene. He could not have been more clear: "I am not saying that polypropylene causes cancer." Dep. at 61:24-62:1. To remove all doubt, he confirmed that he testified in the past that he cannot say to a reasonable degree of medical certainty that polypropylene creates a risk of cancer. *Id.* at 62:3-7. Dr. Reeves' admissions are reason alone to preclude him from testifying regarding any risk of cancer.

***Second*, there is, in fact, no reliable scientific basis for an opinion that polypropylene can cause cancer**. Dr. Reeves cites a number of articles in his Report that purportedly support the causal connection between cancer and polypropylene, but all his citations are to a deposition of a Bard employee, not an article. Dr. Reeves conceded in his Deposition that the citations in his Report were incorrect and he could not identify the articles that support this purported causal connection. *See* Dep. at 62:8-16. Nonetheless, even if Dr. Reeves correctly cited the articles he has referenced in prior reports, none of the articles come even close to establishing that polypropylene mesh presents a cancer risk. Three of the articles did not report cancer at all. *See* November 3, 2014 Deposition of Dr. Keith Reeves ("2014 Deposition" or "2014 Dep.") at 206:16-207:7.[7] Other articles reported four cases of malignancy, but three of the cases did not involve

[7] A true and correct copy of the 2014 Deposition transcript is attached to the Motion as Exhibit D.

polypropylene. *See id*. at 207:9-210:15. The fourth case involved a tumor that developed after abdominal sacral colpopexy using polypropylene, but the reporting physicians wrote that "[i]t is unlikely that the mesh is a causative agent." *Id*. at 208:4-19. Finally, Dr. Reeves cited a monograph, but he had not read it and did not write that part of his report. *Id*. at 211:3- 212:8. When asked whether the monograph reported any human data (which it does not), Dr. Reeves answered that he did not know and repeated that he is "not postulating a cause-and-effect relationship between polypropylene and human cancer." *Id*. at 211:25-212:22. Dr. Reeves therefore cited *only a single case report* of cancer following treatment with polypropylene mesh, and in that report the treating physicians did *not* suspect polypropylene. This is not a basis upon which to draw any valid scientific conclusion, let alone form admissible expert opinion.

***Third*, a cancer risk is irrelevant and the opinion does not fit Plaintiff's case**. Plaintiff does not have cancer and there is no allegation or opinion to the contrary. Any opinion on a purported risk of cancer therefore is irrelevant and inadmissible.[8]

III. THE COURT SHOULD EXCLUDE NARRATIVE REVIEWS OF CORPORATE DOCUMENTS THAT PURPORT TO ADDRESS BARD'S KNOWLEDGE, STATE OF MIND, OR CORPORATE CONDUCT.

As this Court has held on numerous occasions, "a narrative of corporate documents in support of [expert's] opinions regarding Bard's knowledge, state of mind, or corporate conduct … do[es] not assist the jury." *In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2187, 2018 WL 514753, at *3 (S.D. W. Va. Jan. 23, 2018). This Court has repeatedly refused to allow

[8] For related reasons, any reference to cancer should be precluded also under Federal Rule of Evidence 403. The probative value is zero, and it would be heavily outweighed by the unfair prejudice created by testimony that Bard's Alyte device is associated with cancer, an inherently alarming and inflammatory medical term. Testimony on cancer would also confuse the jury. *See Jones*, *supra* slip op. at 8 n.4 (excluding Dr. Ostergard's opinions on cancer under Rule 403 and for lack of relevance or "fit"); *see also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 562 (S.D. W. Va. 2014), *as amended* Oct. 29, 2014 (excluding Dr. Ostergard's opinion on cancer for similar reasons).

"the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably." *Sanchez v. Boston Sci. Corp.*, C.A. No. 2:12-cv-5762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014), *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014).

As the Court previously held, "Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding such "pervasive" opinions in Dr. Shull's report). Further, the Court has consistently held that proffered expert testimony which "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness" is properly excluded. *Id*. at 608 (quoting *Hines v. Wyeth*, No. 2:04–0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011)). *See also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 705-706 (S.D. W. Va. 2014) (excluding expert opinion that was based on expert's review of corporate "deposition testimony and internal documents"); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony ... [t]he question of intent is a classic jury question and not one for the experts.")

In *Huskey*, 29 F. Supp. 3d at 703, the Court stated: "I will not repeatedly parse the expert reports and depositions of each expert in relation to this same objection. I trust that able counsel in this matter will tailor expert testimony at trial accordingly." The same holding should apply here – and Bard should similarly not be required to parse through Dr. Reeves' Report and Deposition transcripts in order to identify every instance of excludable testimony for the Court. Instead, the Court should exclude this testimony wholesale.

To illustrate, large portions of Dr. Reeves' Report are exactly what this Court has not allowed: A narrative of Bard's purported conduct and state of mind. The Report describes, for example, a purported "scheme" to deceive suppliers; how Bard was "concerned" about its supply chain; how Bard "recognized" or "knew" about purported risks; how Bard was "clearly aware" of certain medical literature; how Bard has "known for many years" about available materials; how Bard "did learn" about the significance of pore sizes; and the "Bard company dogma." *See, e.g.*, Report at 2-3, 6, 8-9, 11, 14, 21. The Report on its face confirms that these opinions were a constructed narrative from a review of Bard company documents. Dr. Reeves admitted time and again in his deposition that he was drawing inferences from company documents to build his adopted story. *See, e.g.,* Dep. at 93:20-94:8. For example, in connection with Bard's purchase of polypropylene resin, Dr. Reeves testified,

> The documents that I cited when I was writing this. And this was -- you know, a lot of this was from prior -- this was -- the language that I use here is not original in my report. This is used in previous depositions that I had given. And I did not -- and this information was provided to me. I did not come up with the trial transcripts. I don't have any way of getting that. **I was given this information**.

Id. at 59:7-14 (emphasis added). Dr. Reeves further admitted that he did not personally review the company documents to construct his narrative. *See id.* at 59:15-21. This is consistent with Dr. Reeves' prior testimony where he conceded that these portions of his report were prepared primarily by attorneys, not Dr. Reeves, which is a highly questionable practice under Rule 26. *See* Fed. R. Civ. P. 26(a)(2)(B) (calling for reports "prepared and signed by the witness"); 2014 Dep. at 67:17-22 ("Q. So is it fair to say that the material with regard to Bard's knowledge and conduct and the citations to Bard's documents was primarily the work of Mr. Potts and his colleagues? [Objection] A. I think yes."). Thus, consistent with its many prior rulings, the Court should preclude such testimony as an improper topic of expert opinion. This includes all of Dr. Reeves'

opinions regarding the Material Safety Data Sheet ("MSDS") as Dr. Reeves' deposition testimony made clear that the basis for all of those opinions were company documents and testimony that were provided to him by counsel and he disclaimed any expertise to opine on the MSDS issues. *See* Dep. at 50:3-11, 51:20-21, 54:13-61:7.

IV. THE COURT SHOULD PRECLUDE DR. REEVES FROM OFFERING OPINIONS REGARDING THE ADEQUACY OF THE WARNINGS FOR THE ALYTE BECAUSE HE HAS NO BASIS TO OFFER SUCH OPINIONS.

This Court has not permitted plaintiffs' experts to testify about alleged inadequacies in the IFU for Bard's products or that Bard did not provide adequate warnings absent a scientific and/or regulatory foundation. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 611-12. Dr. Reeves ignores this directive. He opines that Bard failed to provide adequate warnings for the Alyte through documents such as the Instructions for Use ("IFU") and patient brochure by failing to adequately disclose all known adverse reactions and risks. *See* Report at 12.

Courts regularly exclude the expert opinions of medical doctors offering opinions on product labeling when, as is the case here, the doctor has no experience drafting warnings. *See, e.g.*, *Ralson v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969-70 (10th Cir. 2001) (affirming the exclusion of an oncologist opining about the adequacy of labeling because the expert witness had no experience drafting device labeling); *In re: Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at *14, *20 (E.D. Pa. Feb. 1, 2001) (finding that experts were not qualified to testify about the adequacy of drug labeling because they did not have proper experience with labeling of drugs). Dr. Reeves therefore should not be permitted to offer opinions on the Alyte warnings, including opinions on their adequacy, given that he has never drafted an IFU, he is unfamiliar with the FDA's process of clearing an IFU, and the intricacies of FDA standards for what subjects should be included in the IFU and manner in which that information is to be

presented is beyond his experience and expertise. *See id*. at 40:6-7, 116:15-22 ("I'm sure it's laborious, but I'm not intimately familiar with it.").

This Court has not permitted plaintiffs' expert physicians to testify about alleged inadequacies in the IFU for Bard's products, or that Bard did not provide surgeons with adequate warnings, merely because the witness is a physician. *In re C.R. Bard, Inc*., 948 F. Supp. 2d at 611 (excluding Dr. Shull's IFU and warning opinions "[d]espite his stellar qualifications as a urogynecologist"); *Sanchez*, 2014 WL 4851989, at *31 (excluding Dr. Slack's IFU and warning opinions); *Tyree*, 54 F. Supp. 3d at 550-551 (excluding Dr. Ostergard's opinions on product warnings). The Court has consistently excluded opinions regarding the alleged inadequacy of product labeling or warnings absent "authority supporting or explaining why certain information is required." *Sanchez*, 2014 WL 4851989, at *32 (excluding Dr. Slack's "mere speculation and personal belief"); *In re C.R. Bard, Inc*., 948 F. Supp. 2d at 611 ("Strikingly absent from this discussion is any *basis* for Dr. Shull's opinion of what Bard 'should have' done.") (italics in original); *Tyree*, 54 F. Supp. 3d at 551 (noting Dr. Ostergard's "understanding of medical device warnings does not exceed the knowledge of physicians in general").

In addition to providing a reliable scientific basis for including the allegedly required information, at a minimum, opinions about what should or should not be included in product labeling must be grounded in identifiable, reliable, and consistently applied "principles or methods." *Sanchez*, 2014 WL 4851989, at *32. Platitudes like "the standard of care," "a matter of ethics," or "should have gone further" are insufficient for Daubert purposes. *Id*. at *35-*36 (excluding Dr. Pence's labeling opinions); *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 697 (S.D. W. Va. 2014) (adopting same holding regarding Dr. Pence).

Dr. Reeves is a retired physician, but as this Court has held, that alone does not qualify him to opine on medical device warnings. *Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998) (plaintiffs must demonstrate that he is qualified "as an expert in a *particular scientific field*") (emphasis added); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *5 (S.D.W. Va. Aug. 26, 2016) (Goodwin, J.) (excluding expert who did not have the "experience or knowledge on the appropriate testing a medical device manufacture should undertake"). This is particularly true here because Dr. Reeves has never implanted the Alyte device and has never implanted *any* synthetic mesh either transabdominally or transvaginally to treat pelvic organ prolapse. *See* Dep. at 33:7-9, 139:12-18. Dr. Reeves has no idea whether the FDA would ever approve the warnings he claims were lacking and thus his opinion is impermissible speculation. *See id.* at 116:15-22.

Because Dr. Reeves has no expertise or basis upon which to give opinions related to the Alyte IFU, the Court should follow its previous rulings and exclude Dr. Reeves' opinions.

V. THE COURT SHOULD PRECLUDE DR. REEVES FROM OFFERING OPINIONS REGARDING THE ENGINEERING CHARACTERISTICS OF THE ALYTE DEVICE BECAUSE HE HAS NO BASIS TO OFFER SUCH OPINIONS.

Dr. Reeves also opines on various engineering topics and the physical properties of the Alyte mesh, including that the device is prone to roping, cording, curling, fraying, shrinking, having particle loss, and having fibrotic bridging. *See* Report at 21. Dr. Reeves, however, has no expertise in the design or properties of surgical mesh, has never implanted an Alyte mesh, and has performed no testing or analysis of the Alyte mesh. He therefore should not be allowed to give these opinions.

In the Fourth Circuit, courts stress the importance of formal training and the purported experts' relevant practical experience concerning the precise issues for which they are offered. *See, e.g.*, *United States v. Beasley*, 495 F.3d 142, 150 (4th Cir. 2007) (expert's training and

experience, *i.e*. training on identification of narcotics, showed that he was amply qualified to testify on the process of turning power cocaine into crack cocaine). Consistent with this authority, and as with opinions regarding the adequacy of product labeling or warnings, this Court has consistently excluded opinions relating to product design and testing that lack a scientific and/or regulatory foundation and amount only to the "personal opinion" of the witness. *Sanchez*, 2014 WL 4851989, at *31 (excluding Dr. Slack's "unsupported personal opinion"); *Lewis v. Ethicon, Inc.*, No. 2:12– cv–4301, 2014 WL 186872, at *18-19 (S.D. W. Va. Jan. 15, 2014) (excluding Dr. Pence's testing opinions as lacking a "reliable methodology 'reliably applied' . . . to the facts of the case") (citation omitted); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612-613 (excluding Dr. Shull's testimony on design, testing and materials based only on personal experiences and observations and internal Bard documents); *id*. at 631 (excluding Dr. Kessler's "personal opinion" regarding need to conduct human clinical trials); *Huskey*, 29 F. Supp. 3d at 711 (excluding Dr. Pandit's testing opinions because "he cites no scientific support for these opinions").

Dr. Reeves should not be allowed to testify regarding engineering aspects of the Alyte mesh. ***First*, Dr. Reeves is not an engineering expert and is not qualified to offer such opinions**. He intends to opine that the Alyte mesh can deform (*i.e.*, curl or become like a cord or rope) during and after implantation (*see* Report at 6), but he has never implanted an Alyte product or any other synthetic mesh product for pelvic organ prolapse repair. *See* Dep. at 33:7-9, 139:12-18. He also has never designed a pelvic mesh device, is not an expert in the design of pelvic mesh or polypropylene-based devices, and has never published a paper or given a presentation on mesh products like the Alyte. *See id.* at 31:11-32:18, 39:8-9, 41:1-7. Dr. Reeves also has no formal training in bioengineering, materials sciences, or polymer science, and does not consider himself to be an expert in such fields. *See id*. at 38:2-17.

***Second*, Dr. Reeves has no reliable scientific basis for his engineering opinions.** In addition to lacking any qualifications, Dr. Reeves' Report and Depositions are devoid of any testing that would support his opinions regarding the properties of the Alyte product. He does not cite any testing that he did on the shrinkage or contracture of synthetic mesh, on the tensile strength of synthetic mesh, on the flexibility or elasticity of synthetic mesh, or on any other properties of synthetic mesh. Dr. Reeves also did not do any testing on cording, roping, and fraying, and he did not review testing that Bard has done on polypropylene medical devices. *See* Dep. at 98:18-99:4. Significantly, Dr. Reeves did no testing to confirm his hypothesis that the Alyte mesh is prone to curling, cording, roping, and fraying because "[i]f I had a piece of mesh here, I could show you. But if you – it's flat, to begin with, and you pull on it and put it under tension, instead of staying flat, the edges tend to curl in from side to side so that what started out as something that's flat -- if I can use my hands to demonstrate it. This is flat. When it's stretched on either side, it curls in like so." *Id*. at 87:3-9. But pulling on a piece of polypropylene mesh in a law firm conference room is not scientific testing.

Dr. Reeves is well beyond his experience and expertise in giving opinions on the physical properties of the Alyte mesh, including that it is prone to roping, cording, curling, fraying, shrinking, having particle loss, and having fibrotic bridging. He also has no reliable scientific basis for those opinions.[9] This Court therefore should preclude him from giving such opinions.

[9] Even if Dr. Reeves had a reliable or scientific basis to offer these generic design opinions regarding the Alyte (which he does not), Dr. Reeves still needs to tie these alleged general design defects to the specific injuries sustained by Plaintiff. If Dr. Reeves cannot make that connection, then Dr. Reeves' opinion should be excluded because his opinions do not fit the facts of the case. *See Daubert*, 509 U.S. at 591.

VI. THE COURT SHOULD EXCLUDE DR. REEVES' OPINIONS REGARDING SAFER FEASIBLE ALTERNATIVE DESIGNS TO THE ALYTE.

Dr. Reeves' "safer alternatives" opinions should be excluded because the "alternatives" he identifies are either (1) not designs but rather alternative procedures or (2) not feasible because the alternative products did not exist.

It is not sufficient to argue that an entirely different product – or no product at all – should have been used. A "safer alternative design" for purposes of Plaintiff's design defect claim refers to a substitute product design, not an "entirely different product" – even one that "has the same general purpose as the allegedly defective product." *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770–71 (Tex. App. 2009); *see also Massa v. Genentech Inc.*, C.A. No. H-11-70, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (alternative surgical method that did not utilize mesh is not an alternative design); *Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (argument that surgery without the medical device is safer alternative "really takes issue with the choice of treatment made by [plaintiff's] physician, not with a specific fault of the [device] sold by [defendant].").

Here, Dr. Reeves' proposed alternatives either were not available or were completely different surgeries. First, Dr. Reeves proposes using "industrial grade polypropylene as opposed to medical grade polypropylene." Report at 20. Not only does Dr. Reeves fail to cite anything to support the opinion that "medical grade polypropylene" is safer and more effective than "industrial grade polypropylene" but during his deposition Dr. Reeves could not even distinguish the two:

> Q. What is -- [industrial-grade polypropylene as opposed to medical-grade polypropylene] -- are those terms of art?
>
> A. I have looked to try to see where I came up with that, and I actually did a literature Google search to see if I could come up with the definition of the difference between industrial-grade

> polypropylene and medical-grade polypropylene. And I think it has to do with the degree of impurity in the medical grade, but I cannot give you further citations there. It's hard to find.

Dep. at 145:10-24; *see also* Report at 20. Dr. Reeves' opinion here is utterly unreliable. He cannot provide a definition for "medical grade polypropylene" and "industrial grade polypropylene" and does not even attempt to identify an alternative product that was on the market at the same time as the Alyte that used "medical grade polypropylene." Thus, the Court should exclude this opinion.

Second, Dr. Reeves proposes "native tissue repair using the patient's own tissue." Report at 20. A native tissue repair, however, is not an alternative design. It is an alternative procedure. Indeed, Dr. Reeves agrees. *See* Dep. at 146:1-5 ("Q. Okay. Fair enough. And would you agree with me that native tissue repair using the patient's own tissue is not really an alternative design but an alternative procedure? A. Sure."). This Court has excluded opinions related to surgical procedures, rather than alternative product designs, because such alternatives are not relevant. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017) (holding that "*alternative procedures* are irrelevant to the question of whether a safer alternative *design* of a product exists" and excluding plaintiff's expert testimony on "alternative procedures") (emphasis in original). The Court's ruling in *Goodyear* is consistent with and fully supported by this Court's related rulings in similar cases. For example, in *Mullins*, this Court concluded under West Virginia law that "an alternative, feasible design must be examined in the context of products—not surgeries or procedures." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D. W. Va. 2017). Thus, whether an alternative procedure like a native tissue repair could have been performed instead of implanting the Alyte does nothing to inform the jury on the issue of alternative feasible design for the Alyte. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liability Litig.*, 2017 WL 1264620, at *3.

Finally, Dr. Reeves' proposal to use "pelvic organ prolapse products consisting of either cadaveric or porcine material" fails for the same reason. Neither porcine and cadaveric tissue are mesh products, but rather are alternative procedures. *See Schmidt*, 2013 WL 3802804, at *2 ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support this particular claim.").

Therefore, Dr. Reeves' "safer alternatives" opinions should be excluded because he fails to identify an alternative feasible design for the Alyte.

VII. THE COURT SHOULD EXCLUDE DR. REEVES' OPINIONS REGARDING PRODUCT TESTING AND CLINICAL TRIALS.

This Court has consistently excluded opinions regarding product testing that are based on personal opinion rather than a scientific and/or regulatory foundation. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 612. Dr. Reeves opines that Bard's testing on the Alyte "flies in the face of how medical products should be placed on the medical market." Report at 10. Dr. Reeves elaborated in his Deposition that it is his opinion that "[a] surgical implant should not reach the market unless it has first gone through double-blind, prospective studies." Dep. at 111:9-15.

As Dr. Reeves' opinions shows, he is not an expert in FDA regulations, has never prepared a 510(k) or premarket approval application, and has no understanding of the requirements of a 510(k) application. *See* Dep. at 39:10-18. Dr. Reeves seemingly recognizes that his personal opinion regarding what premarket testing should have been done for the Alyte conflicts with FDA regulations:

> Q. And so what is -- what is the basis for your -- your opinion that, in order to have a product go to market showing safety and efficacy -- are you saying that for any implanted surgical product to enter the U.S. market it must be subjected to a double-blind, prospective study?
>
> A. You know, that puts me at odds with the 510(k) process. And as I've told you, I'm not going to go there.

Dep. at 109:3-11. While Dr. Reeves is entitled to his personal opinion, that alone is not sufficient to withstand *Daubert* scrutiny when it lacks a scientific and regulatory foundation. Thus, the Court should exclude Dr. Reeves' opinions regarding Bard's product testing for the Alyte. *See Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *16-17 (S.D. W. Va. Feb. 7, 2015); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D.W. Va. July 8, 2014) (excluding the opinions of Drs. Blavias and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing).

VIII. THE COURT SHOULD EXCLUDE DR. REEVES' OPINIONS THAT STATE A LEGAL CONCLUSION OR PROVIDE LEGAL CONCLUSIONS

The Court has "diligently applied" the rule that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *Sanchez*, 2014 WL 4851989, at *4 (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)); *Tyree*, 54 F. Supp. 3d at 561-562. The Fourth Circuit has explained that the "role of the district court . . . is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion." *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002). "The best way to determine whether opinion testimony contains legal conclusions, 'is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.'" *Id*. (quoting *Torres v. County of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)).

The Court has consistently applied these principles to exclude opinions couched in legal terminology or conclusions. *See Eghnayem*, 57 F. Supp. 3d at 697 (reaffirming prior decisions and declining to parse through the excludable testimony). The Court's rulings have applied regardless of whether the witness is a clinician, *see Sanchez*, 2014 WL 4851989 at *30 (excluding

Dr. Mays' opinions phrased as legal conclusions); *Lewis*, 2014 WL 186872, at *21 (excluding Dr. Rosenzweig's opinion that manufacturer "failed to act as a reasonable and prudent medical device manufacturer" as improper legal opinion), or whether the witness purports to be a regulatory expert, *see In re C.R. Bard, Inc*., 948 F. Supp. 2d at 629 ("The questions of whether Bard's Avaulta products were not reasonably safe, for example, or whether Bard failed to warn, are questions for the jury, not for Dr. Kessler."); *id*. ("Dr. Kessler may not testify that Bard violated FDA regulations.").

Dr. Reeves' Report is replete with statements such as: the Alyte "is defective and unreasonably dangerous"; "Bard failed to act as a reasonable and prudent medical device manufacturer"; "Bard deviated from the standard of care required of a reasonable medical device manufacturer by failing to disclose adequately Alyte's known adverse reactions and risks to physicians." Report at 1, 7, 12. Because statements such as these invoke legal standards and purport to give legal conclusions, the Court should preclude them and any similar statements. Indeed, Dr. Reeves disclaimed in his deposition that he was offering any legal opinions in this case. *See* Dep. at 47:17-19 ("[I'm] not qualified to do that"). Therefore, the Court should exclude every legal standard or conclusion in Dr. Reeves' Report and Deposition.

CONCLUSION

For all of the foregoing reasons, Bard respectfully requests that the Court exclude or limit certain opinions and testimony of Dr. Keith Reeves as set forth above.

Dated: January 23, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2020, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Mildred Segura
Mildred Segura